

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

IN RE: '318 PATENT INFRINGEMENT	)	
LITIGATION	)	Civil Action No. 05-356-KAJ
	)	(consolidated)
	)	
	)	
	)	

**STIPULATED PROTECTIVE ORDER**

WHEREAS Plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P. and Synaptech, Inc. (collectively, "Plaintiffs" or "Janssen") and Defendants Alphapharm Pty Ltd. ("Alphapharm"), Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. (collectively, "Barr"), Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "Dr. Reddy's"), Mylan Pharmaceuticals Inc. and Mylan Laboratories Inc. (collectively, "Mylan"), Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively, "Par"), Purepac Pharmaceutical Co. and Alparma, Inc. (collectively, "Purepac"), and Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, "Teva") (collectively, the "Defendants") are parties to the above-referenced patent infringement case;

WHEREAS Janssen, Alphapharm, Barr, Dr. Reddy's, Mylan, Par, Purepac, and Teva compete in the pharmaceutical industry, and discovery in this civil action, Case No. 05-356-KAJ (hereinafter, the "Litigation") will involve the disclosure of certain documents, things and information in the possession, custody or control of the Plaintiffs, the Defendants, or non-parties, that constitute or contain trade secrets or other confidential research, development or commercial information within the meaning of Federal Rule of Civil Procedure 26(c)(7);

WHEREAS such confidential information must be protected in order to preserve the legitimate business interests of the parties or non-parties;

WHEREAS the parties have, through counsel, stipulated to the entry of this Protective Order for the purpose of advancing the progress of the Litigation and preventing unnecessary dissemination or disclosure of such confidential information; and

WHEREAS the parties have established good cause for entry of this Protective Order;

THEREFORE, for good cause shown, pursuant to Federal Rule of Civil Procedure 26(c), all discovery and other materials exchanged by the parties or non-parties, or filed with the Court, in this Litigation shall be subject to the following conditions:

**I. SCOPE OF PROTECTIVE ORDER**

1. This Protective Order shall apply to all documents, things, or information subject to discovery in this Litigation that is owned, possessed, or controlled by a party or a non-party and that contains the party's or non-party's trade secrets or other confidential research, development, or commercial information ("Confidential Discovery Material"), as set forth under Federal Rule of Civil Procedure 26(c)(7).

**II. CONFIDENTIALITY DESIGNATIONS (TWO-TIER)**

2. Each party and any non-party shall have the right to designate as confidential and subject to this Protective Order any Confidential Discovery Material that is entitled to protection under Federal Rule of Civil Procedure 26(c)(7), by marking such Material as either "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" Material. It shall be the duty of the party or non-party who seeks to invoke protection under this Protective Order to give notice, in the manner set forth in Section III, below, of the Confidential Discovery Material designated to be covered by this Protective Order ("Designated [CONFIDENTIAL or HIGHLY CONFIDENTIAL] Material"). The duty of the other parties and of all other persons bound by

this Protective Order to maintain the confidentiality of Confidential Discovery Material so designated shall commence with such notice.

3. Each party and all other persons bound by the terms of this Protective Order shall use any material designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL by a party or non-party other than itself only for the purpose of this Litigation, and shall not use any Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material governed by this Protective Order for any other purpose. The attorneys of record for the parties shall exercise reasonable care to ensure that the information and documents governed by this Protective Order are (a) used only for the purpose specified herein, and (b) disclosed only to authorized persons.

**“CONFIDENTIAL” Material**

4. Under this Protective Order, Confidential Discovery Material shall be marked as “CONFIDENTIAL” if, and only if, the disclosing party would not disclose the Material to the public in the normal course of business.

5. CONFIDENTIAL Material shall include: (a) all copies, extracts, and complete or partial summaries prepared from CONFIDENTIAL Material; (b) portions of deposition transcripts and exhibits thereto that contain, summarize, or reflect the content of any such CONFIDENTIAL Material; (c) portions of briefs, memoranda, or any other writings filed with the Court and exhibits thereto that contain, summarize, or reflect the content of any such CONFIDENTIAL Material; (d) written discovery responses and answers that contain, summarize, or reflect the content of any such CONFIDENTIAL Material; and (e) deposition testimony designated in accordance with Paragraphs 13-14, below.

**“HIGHLY CONFIDENTIAL” Material**

6. Under this Protective Order, Confidential Discovery Materials can be designated as “HIGHLY CONFIDENTIAL” Material if, and only if, that Confidential Discovery Material is

CONFIDENTIAL Material as set forth in Paragraph 4 above and contains or discloses information relating to, referencing, or pertaining to proprietary information that could do harm to the designating party's business advantage (*e.g.*, business plans, marketing plans, production capacity, launch information, customer lists, and technical information), or otherwise contains or discloses information relating to, referencing, or pertaining to a trade secret or other confidential research and/or development information.

7. HIGHLY CONFIDENTIAL Material shall include: (a) all copies, extracts, and complete or partial summaries prepared from HIGHLY CONFIDENTIAL Material; (b) portions of deposition transcripts and exhibits thereto that contain, summarize, or reflect the content of any such HIGHLY CONFIDENTIAL Material; (c) portions of briefs, memoranda, or any other writings filed with the Court and exhibits thereto that contain, summarize, or reflect the content of any such HIGHLY CONFIDENTIAL Material; (d) written discovery responses and answers that contain, summarize, or reflect the content of any such HIGHLY CONFIDENTIAL Material; and (e) deposition testimony designated in accordance with Paragraphs 13-14, below.

### **III. DESIGNATING MATERIALS AS “CONFIDENTIAL” AND/OR “HIGHLY CONFIDENTIAL”**

#### **Documents and Things**

8. “CONFIDENTIAL” Material: The party or non-party producing any documents or things containing CONFIDENTIAL Material who seeks to invoke protection under this Protective Order for that Material shall designate that Material by stamping or labeling each page of the document or thing with either the legend “CONFIDENTIAL” or “CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER” at the time the document or thing, or a copy thereof, is provided to the requesting party.

9. “HIGHLY CONFIDENTIAL” Material: The Designating Party may designate certain information for the higher level of confidentiality set forth in Paragraph 6, above, by stamping or labeling each page of that document or thing “HIGHLY CONFIDENTIAL” or “HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER.” The provisions of this Order that apply to CONFIDENTIAL Material also apply to material marked “HIGHLY CONFIDENTIAL.”

10. The inadvertent failure by a producing party to designate specific documents or things as containing CONFIDENTIAL or HIGHLY CONFIDENTIAL Material shall not be deemed a waiver in whole or in part of a claim of confidentiality as to such documents or things. Upon notice to the receiving party of such failure to designate, the receiving party shall cooperate to restore the confidentiality of the inadvertently disclosed information. With respect to all documents or things provided for inspection by a party’s or non-party’s counsel, designation by stamping or labeling as CONFIDENTIAL or HIGHLY CONFIDENTIAL need not be made until copies of the documents or things are produced after inspection and selection by counsel. Making documents or things available for inspection shall not constitute a waiver of any claim of confidentiality, and all materials provided for inspection by a party’s or non-party’s counsel shall be treated as though designated as HIGHLY CONFIDENTIAL at the time of the inspection.

#### **Deposition Transcripts and Exhibits**

11. Testimony provided in a deposition and deposition exhibits may be designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL Material subject to this Protective Order either (1) during the deposition, or (2) by written notice to the reporter and all counsel of record provided within fourteen (14) days after the deposition transcript is received by the designating party or non-party, in which case all counsel receiving such notice shall be responsible for

marking the copies of the designated transcript in their possession or under their control as directed by the designating party or non-party. Until expiration of that fourteen (14) day period, the entire deposition and all exhibits thereto will be treated as HIGHLY CONFIDENTIAL under this Protective Order. If no party or non-party timely designates as CONFIDENTIAL or HIGHLY CONFIDENTIAL any information provided in a deposition, then none of the transcript or exhibits (unless previously designated CONFIDENTIAL or HIGHLY CONFIDENTIAL) will be treated as confidential; if a timely designation is made, the confidential portions and exhibits, and all copies of those portions and exhibits, shall be treated as Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material pursuant to the terms of this Protective Order. Deposition exhibits previously designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL do not need to be redesignated to retain their protection under this Protective Order.

12. Deposition transcripts containing testimony with Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material shall be prominently marked on the front page with a statement that provides "THIS DEPOSITION TRANSCRIPT CONTAINS [HIGHLY] CONFIDENTIAL INFORMATION THAT IS SUBJECT TO PROTECTIVE ORDER." Any deponent may review the transcript from his/her own deposition that has been designated CONFIDENTIAL or HIGHLY CONFIDENTIAL to ensure that it is accurate and complete, but no deponent, other than individuals described in Paragraph 15, below, may retain or copy any portion of the transcript of the depositions that contains Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material without written permission of the designating party.

#### **Deposition Testimony**

13. At any deposition session, when counsel for a party or non-party deems that the answer to a question will result in the disclosure of Confidential Discovery Material, counsel

shall have the option, in lieu of or in addition to taking other steps available under the Federal Rules of Civil Procedure, to direct that the testimony shall be treated as Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material and subject to this Protective Order.

14. Counsel for the party or the non-party whose Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material is involved may also request that all persons other than the reporter, the witness, counsel, and individuals specified in Paragraph 15, below, who may have access to such Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material, leave the deposition room during the confidential portion of the deposition. The failure of such other persons to comply with a request of this type shall constitute substantial justification for counsel to advise the witness that the witness need not answer the question.

#### **IV. PERSONS WITH ACCESS TO “CONFIDENTIAL MATERIAL” AND “HIGHLY CONFIDENTIAL” MATERIAL**

15. Subject to the conditions set forth below, the following persons shall have access to materials marked CONFIDENTIAL and/or HIGHLY CONFIDENTIAL by a designating party:

- a. The Court and its official personnel;
- b. The non-designating party’s “Outside Counsel” including:
  - i. Counsel who have filed appearances in this Litigation and their law firms’ active members, associate attorneys, paralegals, and office staffs working on this case (“Counsel of Record”); and
  - ii. Counsel, other than In-House Counsel (as defined below in Paragraph 15.c.) and Counsel of Record (*see* subparagraph b(i) above), who are assisting in the Litigation and their law firms’ active members, associate attorneys, paralegals, and office staffs working on this Litigation (“Assistant Counsel”). However, before such

Assistant Counsel may have access to any CONFIDENTIAL or HIGHLY CONFIDENTIAL Material, he/she must execute a copy of the Highly Confidential Undertaking or the Confidential Undertaking, both attached hereto, and circulate the Undertaking to counsel for all parties to this Litigation. If no objection is received from any Designating Party within five (5) days of receiving the executed Undertaking (or such shorter time period as may be agreed), the Assistant Counsel may have access to CONFIDENTIAL and/or HIGHLY CONFIDENTIAL Material (depending on the form of the Undertaking executed by the individual);

c. Subject to the conditions set forth below, up to three (3) in-house attorneys from the non-designating party (attorneys employed by the non-designating party or by that party's corporate affiliate and who serve in the role of in-house counsel) or, in the event a non-designating party does not have any in-house attorneys, up to three (3) current employees who are working on or have direct responsibility for directing and/or supervising this Litigation ("In-House Counsel"), so long as any such attorney or employee has executed either a copy of the Confidential Undertaking or a copy of the Highly Confidential Undertaking, both attached hereto, and such executed Undertaking is circulated to counsel for all parties to this Litigation.

If no objection is received from any Designating Party within five (5) days of receiving an executed Undertaking (or such shorter time period as may be agreed), the In-House Counsel designated specifically as follows may have access to CONFIDENTIAL and/or HIGHLY CONFIDENTIAL Material (depending on the form of Undertaking executed by the individual), subject to the conditions set forth below:



- for Janssen: Steven P. Berman; Taysen Van Itallie; Peter Herridge
- for Alphapharm: Dr. Howard Rosenberg; Dr. Paul Jenkins
- for Barr: Fred Killion; Ling Zeng
- for Dr. Reddy's: Andrew Miller; Lee Banks; Sumesh Reddy
- for Mylan: Jill Ondos; Stuart A. Williams
- for Par: Petur Hansson; Martin Wilson
- for Purepac: Terri Nataline; Ken Smith; Robert Wrobel
- for Teva: Richard Egosi; David Stark; Staci Julie

i. In-House Counsel for Janssen shall be allowed access to material designated by any Defendant or non-party as CONFIDENTIAL;

ii. In-House Counsel for any Defendant shall be allowed access to material designated by Janssen or a non-party as CONFIDENTIAL;

iii. In-House Counsel for any Defendant shall not have access to material designated by any other Defendant as CONFIDENTIAL without first obtaining written consent from the designating Defendant or by Order of the Court;

iv. In-House Counsel for Defendants (as defined under this Paragraph 15.c.) may not have access to any other Defendant's HIGHLY CONFIDENTIAL Material. In-House Counsel for Janssen (as defined under this Paragraph 15.c.) may have access to any Defendant's or non-party's HIGHLY CONFIDENTIAL Material and In-House Counsel for Defendants (as defined under this Paragraph 15.c.) may have access to any of Janssen's or a non-party's HIGHLY CONFIDENTIAL Material only if they (a) execute and serve on all parties the Highly Confidential Undertaking, and (b) receive no objection from any Designating Party within five (5) days of the Designating Party's

receipt of the executed Highly Confidential Undertaking, and (c) are in compliance with the following limitations:

- (1) No In-House Counsel for Janssen and no In-House Counsel for Defendants who have participated in, are currently participating in, or will participate in the preparation and/or prosecution of patents or patent applications (including but not limited to making prosecution decisions, such as the scope of claims) concerning galantamine or galantamine products may have access to any other party's HIGHLY CONFIDENTIAL Material;
- (2) No In-House Counsel for Janssen and no In-House Counsel for Defendants who have had, currently have, or will have responsibility for and/or direct involvement in the research, development, marketing, commercialization, promotion or sale of galantamine or galantamine products may have access to any other party's HIGHLY CONFIDENTIAL Material; and
- (3) No In-House Counsel for Janssen and no In-House Counsel for Defendants who have communicated with, are in ongoing communication with, or will communicate with regulatory authorities including, but not limited to, the United States Food and Drug Administration (FDA) regarding galantamine or galantamine products may have access to any other party's HIGHLY CONFIDENTIAL Material.

Persons who are entitled to have access to HIGHLY CONFIDENTIAL Material also shall be entitled to have access to CONFIDENTIAL Material.

Notwithstanding the above limitations on In-House Counsel (as defined under this Paragraph 15.c.) who may have access to HIGHLY CONFIDENTIAL Material, In-House Counsel (as defined under this Paragraph 15.c.) for Janssen or In-House Counsel for Defendants who fall within the 3-per-party limitation and who wish to have access to CONFIDENTIAL Material, but not to HIGHLY CONFIDENTIAL Material, may have access to CONFIDENTIAL Material so long as any such attorney or employee has executed and circulated a copy of the Confidential Undertaking attached hereto, and if no

objection is received from any Designating Party within five (5) days of receiving the executed Confidential Undertaking (or such shorter time period as may be agreed), have access to any other party's CONFIDENTIAL Material, subject only to the restriction in Paragraph 15.c.(iii) above.

v. If a dispute arises as to the disclosure of any materials to In-House Counsel under this Paragraph 15.c., and the relevant parties are unable to resolve the dispute, the party seeking to make any disclosure of CONFIDENTIAL or HIGHLY CONFIDENTIAL materials must file a motion with the Court (and serve such motion on all parties to this Litigation) seeking an order allowing the disclosure to take place. The burden of demonstrating good cause for allowing access to any designated material shall lie with the party seeking disclosure (*i.e.*, the non-designating party). Until any such motion is resolved by an order of the Court or agreement in writing of the party seeking to make disclosure and the party or non-party objecting to the disclosure, no disclosure shall be made to the objected-to In-House Counsel.

d. Outside experts and consultants retained by the non-designating party's Outside Counsel (as defined above in Paragraph 15.b.) to assist in this Litigation (and the expert's or consultant's staff, stenographic, and clerical employees whose duties and responsibilities require access to such materials), who are not past or present full-time employees of that non-designating or any other party or of an affiliate of that non-designating or any other party, provided that the conditions set forth in Paragraph 17, below, concerning advance notice are satisfied;

e. Court reporters, translators, third-party photocopy or imaging services contractors, third-party contractors producing graphic or visual aids involved solely in

providing litigation support services to Outside Counsel (as defined above in Paragraph 15.b.);

f. Jury consultants involved solely in providing litigation support services to Outside Counsel (as defined above in Paragraph 15.b.), so long as any jury consultant has executed a copy of the Confidentiality Undertaking attached hereto and such executed Undertaking is circulated to counsel for all parties to this Litigation;

g. At a deposition, any person currently or formerly an officer, director, employee, patent attorney, or patent agent of or for the party or non-party designating the material as confidential, so long as any such person has executed a copy of the Confidentiality Undertaking attached hereto; and

h. Any other person agreed to in writing by the parties so long as any such person has executed a copy of the Confidentiality Undertaking attached hereto.

16. As set forth above, in no event shall any Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material be disclosed to any person allowed access under Paragraphs 15.b.ii, 15.c, 15.f, 15.g (as it relates to former officers, directors, employees, patent attorneys, or patent agents of or for the party or non-party), and 15.h, above, until such person has been shown a copy of this Protective Order and executed a copy of the Confidential Undertaking and/or Highly Confidential Undertaking attached hereto. Confidentiality Undertakings executed by persons under Paragraphs 15.b.ii, 15.c, and 15.f., above, shall be disclosed to all parties to this Litigation prior to the disclosure of Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material. Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material shall not be disclosed to any person who refuses to execute the

written Confidentiality Undertaking attached hereto without prior express written leave of the Court.

**V. PROCEDURES FOR DISCLOSURE OF CONFIDENTIAL AND/OR HIGHLY CONFIDENTIAL INFORMATION TO AN EXPERT OR CONSULTANT**

17. Before counsel for a non-designating party may disclose Material designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL to a person described in Paragraph 15.d., above, that counsel shall give advance notice as follows: Counsel for the non-designating party seeking to make the disclosure shall provide written notice (by facsimile followed by a copy sent the same day by e-mail) to counsel for the designating party or non-party, and all other parties to this Litigation, of the name, address, business affiliation and curriculum vitae of the person(s) to whom the Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material is to be disclosed, as well as an executed copy of the Confidentiality Undertaking attached hereto. Counsel for the non-designating party need not specifically identify the Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material intended to be disclosed.

18. The designating party or non-party shall have seven (7) business days after receiving that notification within which to object to the proposed disclosure, as provided below; such disclosure shall not occur before the time for any objection by the designating party or nonparty expires, and, if any such objection is made, before that objection is resolved, as provided below. Any such objection shall be made in writing (by facsimile followed by a copy sent the same day by e-mail) to the counsel for the party seeking to make the disclosure, and all other parties to the Litigation.

19. If the parties or party and non-party are unable to resolve the objection, and the party seeking to make the disclosure indicates that it still intends to disclose the Material designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL to the person or persons in

question, the designating party or non-party must file a motion with the Court (and serve such motion on all parties to this Litigation) seeking a protective order to prevent the disclosure of such material to such person or persons. Such motion must be filed with the Court within fifteen (15) business days of receiving the initial notification under Paragraph 17, above, unless agreed otherwise, in writing, between or among the counsel involved. The burden of demonstrating good cause for the requested relief shall lie with the objecting party or non-party (*i.e.*, the designating party or non-party). A failure to object or file a motion within the requisite time limits shall be deemed a waiver of the objection. Upon a timely objection and motion, and during the periods set forth above and until any such motion is resolved by Order of the Court or agreement in writing between the party seeking to make the disclosure and the party or non-party objecting to the disclosure, no disclosure shall be made to the objected-to person or persons.

**VI. PROCEDURES FOR DISCLOSURE OF CONFIDENTIAL AND/OR HIGHLY CONFIDENTIAL INFORMATION TO PERSONS NOT COVERED BY PARAGRAPH 15**

20. Before counsel for a non-designating party may disclose Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material to any person, and in any manner, not authorized by Paragraph 15, above, that counsel must give advance notice (by facsimile followed by a copy sent the same day by e-mail) to the designating party or non-party, and all other parties to this Litigation, of the name, address, and business affiliation of the person to whom the Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material is to be disclosed, as well as an executed copy of the Confidential Undertaking or Highly Confidential Undertaking attached hereto.

21. The designating party or non-party shall have ten (10) business days after receiving that notification within which to object to the proposed disclosure, as provided below; such disclosure shall not occur before the time for any objection by the designating party or

nonparty expires, and, if any such objection is made, before that objection is resolved, as provided below. Any such objection shall be made in writing (by facsimile followed by a copy sent the same day by e-mail) to the counsel for the party seeking to make the disclosure, and all other parties to this Litigation. Failure by the designating party or non-party to object within the requisite time limits shall be deemed a waiver of the objection.

22. If the parties or party and non-party are unable to resolve any objection, and the party seeking to make the disclosure indicates that it still intends to disclose the Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material to the person or persons in question, the party seeking disclosure must file and serve a motion with the Court seeking an order allowing the disclosure to take place. The burden of demonstrating good cause for allowing access to the Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material shall lie with the party seeking disclosure (*i.e.*, the non-designating party). Upon a timely objection and motion, and during the periods set forth above and until any such motion is resolved by Order of the Court or agreement in writing between the party seeking to make the disclosure and the party or non-party objecting to the disclosure, no disclosure shall be made to the objected-to person or persons.

## **VII. FILING CONFIDENTIAL OR HIGHLY CONFIDENTIAL MATERIAL**

23. Any Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material, if filed with the Court, shall be filed and kept by the Court under seal and shall be made available only to the Court and to persons authorized by the terms of this Protective Order. The party filing any paper that contains, summarizes, or reflects any Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material shall file such paper in a sealed envelope, or other appropriately sealed container, that indicates: (a) the case caption; (b) the name of the document if it can be disclosed publicly, otherwise an appropriate title by which the document may be

identified on the public docket; (c) the name, address and telephone number of the person filing the document; and (d) the legend CONFIDENTIAL – FILED UNDER SEAL.

24. The parties are also required to follow all applicable local rules concerning confidential or sealed documents. Pursuant to the Electronic Case Filing CM/ECF filing rules of the United States District Court for the District of Delaware in effect at the time of entry of this Protective Order, the party filing a sealed document with the Court shall file electronically a public version of any sealed document within five (5) business days of the filing of the sealed document, redacting only the CONFIDENTIAL or HIGHLY CONFIDENTIAL Material.

### **VIII. MISCELLANEOUS**

25. This Protective Order shall not preclude any party from seeking and obtaining, on an appropriate showing of good cause, such additional protection with respect to the confidentiality of documents, things, or information as that party or non-party may consider appropriate. Nor shall any party be precluded from: (a) claiming that any Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material is not entitled to the protection of this Protective Order; (b) applying to the Court for an Order permitting the disclosure or use of documents, things, or information otherwise prohibited by this Protective Order; or (c) applying for an Order modifying this Protective Order in any respect. No party shall be obligated to challenge the propriety of any confidentiality designation and failure to do so shall not preclude a subsequent attack on the propriety of such designation.

26. The restrictions set forth in this Protective Order shall not apply to documents, things, or information that:

- a. was, is, or will become public knowledge in a manner other than through a violation of this Order; or



b. is lawfully obtained from a third party or independently developed by the non-designating party, as evidenced by written documentation.

27. If a party seeks removal of protection for particular items of Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material on the ground that such protection is not warranted under controlling law, the following procedure shall be used:

a. The party seeking such removal shall give counsel of record for the designating party (as set forth in Paragraph 33, below) or non-party notice thereof, in writing (by facsimile followed by a copy sent the same day by e-mail), specifying the documents, things, or information for which such removal is sought and the reasons for the request. The designating party or non-party shall have ten (10) business days after receiving that notification within which to object to the removal of protection afforded by this Order. Any such objection shall be made in writing (by facsimile followed by a copy sent the same day by e-mail). Failure to object within the requisite time limit is deemed a waiver of any claim to protection for that specific document, thing, or information under this Protective Order.

b. If the parties, or the party and non-party, cannot agree concerning the matter, then the party or non-party seeking the removal of protection for Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material must file and serve a motion with the Court; the designated material shall continue to be Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material until the issue is resolved by Order of this Court or by agreement of the parties or the party and non-party.

c. On any motions arising out of the designation of any material as Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material under this

Protective Order, the burden of justifying the designation shall lie with the designating party or non-party.

28. This Protective Order is intended to provide a mechanism for the handling of Confidential Discovery Material for which there is no objection to disclosure or production other than confidentiality as trade secret or other confidential research, development, or commercial information. Each party reserves the right to object to any production or disclosure of any documents, things, or information it deems confidential on any other ground it may deem appropriate, including, without limitation, the attorney-client privilege or work product immunity.

29. Inadvertent production of documents or information subject to the attorney-client privilege, work product immunity, or any other applicable privilege or immunity shall not constitute a waiver of such privilege(s). Inadvertent production of documents or information shall be handled as follows, but is without prejudice to the right of any party to apply to the Court for further protection or disclosure relating to discovery:

a. Immediately after receiving written notice from the producing party that documents or information subject to the attorney-client privilege, work product immunity, or otherwise immune from discovery has been inadvertently produced, the receiving party shall not copy or disseminate such documents or information, and, subject to Paragraph 29.b. herein, the receiving party shall return such documents or information and any copies to the producing party within fourteen (14) days.

b. Upon written notification by the producing party of an inadvertent production and request for return of all originals and copies, the receiving party shall return the inadvertently produced documents or information (and return or certify in

writing to the destruction of all copies thereof) within fourteen (14) days of receiving the producing party's written request for return, unless the receiving party has a good faith basis for asserting that the information is not protected by any privilege or immunity. If the receiving party believes it has a good faith basis for challenging the privilege claim, the receiving party need not return such material until ordered to do so by a final order of the District Court. Within fourteen (14) days after receipt of the producing party's request for return, counsel of record for the receiving party shall provide counsel of record for the producing party with a written explanation of the good faith basis for refusing to return the inadvertently produced documents or information. In the event that the inadvertently produced documents or information is not returned based upon the receiving party's timely written explanation of the good faith basis for refusing to return those documents or material, the producing party has fourteen (14) days from receipt of the receiving party's written explanation to file a motion seeking an order compelling the return of the inadvertently produced documents or information. Failure of the producing party to file such a motion within fourteen (14) days from receipt of the receiving party's written explanation waives any claim of privilege or immunity as to the inadvertently produced documents or information at issue.

c. Once an inadvertently produced document or information has been used during a deposition, used as an exhibit to a pleading filed with the Court, identified for use at trial or otherwise disclosed to the Court, the producing party has three (3) weeks from the date of disclosure to provide notice of the inadvertent production. Notwithstanding any other provision of this Order, failure to provide notice within this

three (3) week period shall constitute a waiver of any and all applicable privileges with respect to the inadvertently produced documents or information only.

30. Upon final termination of this Litigation, unless otherwise agreed to in writing by counsel of record for the designating party or non-party, each party shall within one hundred and twenty (120) days assemble and return or destroy all Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material, including all copies, extracts, and summaries thereof, to the party or non-party from whom the Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material was obtained, except that counsel of record may retain copies of pleadings and materials that are of record in the litigation, subject to the confidentiality provisions of this Protective Order. All counsel of record shall make certification of compliance herewith and shall deliver the same to counsel for the party or the non-party who produced the documents not more than one hundred and eighty (180) days after the final termination of this Litigation.

31. No part of the restrictions imposed by this Protective Order may be terminated, except by written stipulation executed by counsel of record for each designating party or nonparty, or by an Order of this Court for good cause shown. The termination of this Litigation shall not automatically terminate the directives of this Protective Order.

32. This Protective Order governs the confidentiality of Designated CONFIDENTIAL and HIGHLY CONFIDENTIAL Material before and after trial. If a party intends to disclose Designated CONFIDENTIAL and HIGHLY CONFIDENTIAL Material in Court at any pretrial proceeding open to the public, the issue of whether any such disclosure may be made shall be governed by applicable law or additional Order of this Court. That party, however, shall give counsel for the designating party or non-party notice of that intention, in writing (by facsimile followed by a copy sent the same day by e-mail), at least ten (10) business

days before making such disclosure, and shall identify in that notice the specific material intended to be disclosed to the extent feasible and consistent with legitimate trial strategy considerations.

33. Notices under this Protective Order shall be provided to the parties' respective counsel at their addresses indicated as follows, unless this provision is modified by the parties in writing: notice to Janssen shall be to George Pappas, Christopher Sipes, and Laura McNeill; notice to Alphapharm shall be to Alan H. Bernstein and Mona Gupta; notice to Barr shall be to Taras Gracey, Lynn Ulrich, and Brian Franklin; notice to Dr. Reddy's shall be to Stuart D. Sender and David Lorenz; notice to Mylan shall be to William A. Rakoczy, Christine Siwik, and Amy D. Brody; notice to Par shall be Jacques Smith, Janine Carlan, and John Hsu; notice to Purepac shall be to James P. Barabas; and notice to Teva shall be to Karen Robinson.

34. Nothing in this Protective Order shall prevent or otherwise restrict counsel from rendering legal advice to their clients in this litigation and, in the course thereof, relying generally on examination of Designated CONFIDENTIAL and HIGHLY CONFIDENTIAL Material; provided, however, that in rendering such advice and otherwise communicating with such client, counsel shall not make specific disclosure of any item so designated.

35. No person subject to this Protective Order may disclose, in public or private, any Designated CONFIDENTIAL and HIGHLY CONFIDENTIAL Material designated by a party or non-party other than itself, except as provided for in this Protective Order. Nothing herein, however, shall affect the right of the designating party or non-party to disclose to its officers, directors, employees, consultants, or experts, any documents, things, or information designated by it as CONFIDENTIAL or HIGHLY CONFIDENTIAL material; such disclosure shall not

waive the protection of this Protective Order and shall not entitle other parties or their attorneys to disclose such information, documents, things, or information in violation of this Order.

36. No party shall be responsible to another party for any use made of material that was produced and not designated as Confidential or Highly Confidential.

37. By entering this Protective Order and limiting the disclosure of information in this case, the Court does not intend to preclude another court or an administrative agency from finding that the information may be relevant and subject to disclosure (under subpoena or otherwise) in another case. Any person or party subject to this Protective Order who becomes subject to a subpoena, motion or order to disclose another party's information designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL pursuant to this Protective Order shall promptly (but in no event later than ten (10) business days after receiving said subpoena, motion or order) notify the designating party of the subpoena, motion or order so that the designating party may have an opportunity to appear and be heard on whether that information should be disclosed.

38. Any violation of this Protective Order may constitute a contempt of Court, and be punishable as such, and may subject the offending party or non-party to such additional and further remedies as may be available to the aggrieved party or non-party.

39. Until such time as this Protective Order has been entered by the Court, the parties agree that upon execution by all of the parties, it will be treated as though it has been "So Ordered."

40. The Court retains jurisdiction subsequent to settlement or entry of judgment to enforce the terms of this Protective Order.

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Dated: October 28, 2005

SO ORDERED this \_\_\_\_\_ day of \_\_\_\_\_, 2005

\_\_\_\_\_  
United States District Judge



**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

IN RE: '318 PATENT INFRINGEMENT  
LITIGATION

)  
) Civil Action No. 05-356-KAJ  
) (consolidated)  
)  
)  
)

**CONFIDENTIAL UNDERTAKING**

I, \_\_\_\_\_, being duly sworn, state that:

(a) My present residential address is \_\_\_\_\_

\_\_\_\_\_.

(b) My present employer is \_\_\_\_\_

and the address of my present employer is \_\_\_\_\_

\_\_\_\_\_.

(c) My present occupation or job description is \_\_\_\_\_

\_\_\_\_\_.

(d) I have received and carefully read the Stipulated Protective Order in the above-captioned case, entered by the Court on \_\_\_\_\_, 2005. I certify that I understand the terms of that Protective Order, recognize that I am bound by the terms of that Order, and agree to comply with those terms. Further, I understand that unauthorized disclosure of any Designated CONFIDENTIAL Material, or its substance, may constitute contempt of this Court and may subject me to sanctions or other remedies that may be imposed by the Court and potentially liable in a civil action for damages by the disclosing party.

\_\_\_\_\_

SUBSCRIBED and SWORN to before me  
this \_\_\_\_\_ day of \_\_\_\_\_, 200\_\_.

Notary Public

My Commission Expires \_\_\_\_\_

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

IN RE: '318 PATENT INFRINGEMENT  
LITIGATION

)  
) Civil Action No. 05-356-KAJ  
) (consolidated)  
)  
)  
)

**HIGHLY CONFIDENTIAL UNDERTAKING**

I, \_\_\_\_\_, being duly sworn, state that:

(a) My present residential address is \_\_\_\_\_

\_\_\_\_\_.

(b) My present employer is \_\_\_\_\_

and the address of my present employer is \_\_\_\_\_

\_\_\_\_\_.

(c) My present occupation or job description is \_\_\_\_\_

\_\_\_\_\_.

(d) I certify that:

- I have not participated in, do not currently participate in, and will not participate in the preparation and/or prosecution of patents or patent applications (including but not limited to making prosecution decisions, such as the scope of claims) concerning galantamine or galantamine products;
- I have not had, do not currently have, and will not have responsibility for and/or direct involvement in the research, development, marketing, commercialization, promotion or sale of galantamine or galantamine products; and
- I have not communicated with, am not currently in communication with, and will not communicate with regulatory authorities including, but not limited to, the United States Food and Drug Administration (FDA) regarding galantamine or galantamine products.

(e) I have received and carefully read the Stipulated Protective Order in the above-captioned case, entered by the Court on \_\_\_\_\_, 2005. I certify that I understand the terms of that Protective Order, recognize that I am bound by the terms of that Order, and agree to comply with those terms. Further, I understand that unauthorized disclosure of any Designated CONFIDENTIAL or HIGHLY CONFIDENTIAL Material, or its substance, may constitute contempt of this Court and may subject me to sanctions or other remedies that may be imposed by the Court and potentially liable in a civil action for damages by the disclosing party.

\_\_\_\_\_  
SUBSCRIBED and SWORN to before me  
this \_\_\_\_\_ day of \_\_\_\_\_, 200\_\_.  
Notary Public  
My Commission Expires \_\_\_\_\_